SEP 23 2002

K020571

510(k) Summary for
Stöckert Centrifugal Pump Console

1. SPONSOR

Stöckert Instrumente GmbH
Lindberghstrasse 25
80939 Munich, Germany

Contact: Helmut Höfl, Director, Quality Assurance and Regulatory Affairs
Telephone: 011 49 89 323 010
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Date Prepared: July 9, 2002

2. Device Name

Proprietary Name: Stöckert Centrifugal Pump Console
Common/Usual Name: Cardiopulmonary bypass device
Classification Name: Multiple (*see Table 1*)

Table G-1. SCPC System Classifications

Classification Name	21 CFR	ProCode	Classification
Cardiopulmonary bypass heart-lung console	870.4220	74DTQ	Class II
Cardiopulmonary bypass bubble detector	870.4205	74KRL	Class II
Cardiopulmonary bypass level sensing monitor/control	870.4340	74DTW	Class II
Accessory to the cardiopulmonary bypass console: Temperature Monitor	870.4220	74DTQ	Class II
Accessory to the cardiopulmonary bypass console: Timer	870.4220	74DTQ	Class II
Cardiopulmonary bypass coronary pressure gauge	870.4310	74DXS	Class II

3. Predicate Devices

- Medtronic Bio-Console 540/550 (Multiple)
- RotaFlow Centrifugal Pump System (K991864)
- Himex Centriflow Centrifugal Perfusion Pump System (K972740)
- Stöckert Compact System (K982014)

4. Device Description

The SCPC System provides electrical power and sets specific operational parameters for the Stöckert Centrifugal Pump Control Panel and Drive Unit described in K011838. The SCPC System also monitors the following parameters of the cardiopulmonary bypass circuit:

- Pressure
- Temperature
- Level monitoring/bubble detection
- Elapsed time

The SCPC System provides procedural flexibility for use of the Stöckert Centrifugal Pump, allowing the pump to be used as a component of other legally marketed heart-lung machine consoles.

5. INTENDED USE

The SCPC System is a software-controlled cardiopulmonary bypass device containing an uninterruptable power supply (UPS) and S3 Sensor Modules that is designed for operation of the Stöckert Centrifugal Pump and monitoring the cardiopulmonary bypass circuit. The SCPC System, in combination with the Stöckert Centrifugal Pump and the COBE Revolution Pump Head, is indicated for speed-controlled pumping through the cardiopulmonary bypass circuit for typical durations of six hours or less.

The SCPC System has been qualified only for durations appropriate to cardiopulmonary bypass procedures and has not been qualified through in vitro, in vivo, or clinical studies, for long term use as a bridge to transplant, pending recovery of the natural heart, or extracorporeal membrane oxygenation (ECMO) procedures.

6. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

The proposed SCPC System is identical in intended use and fundamental scientific technology to the cited predicate devices. Both the proposed SCPC System and the predicate devices provide electrical power and set operational parameters of connected pump(s) and monitor critical parameters of the cardiopulmonary bypass procedure. The differences between the proposed and predicate devices are limited to features that raise no new issues of safety or effectiveness.

7. PERFORMANCE TESTING

Electrical safety and electromagnetic compatibility testing was performed to demonstrate conformance with the appropriate standards. Functional acceptance testing, hardware and software testing, and validation testing was performed to confirm that the proposed SCPC System performed as designed and met user requirements, including compatibility with the Stöckert CAPS (K863541), Stöckert S3, and COBE® Century™ (K960974) heart-lung machine (HLM) consoles.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 23 2002

Stöckert Instrumente GmbH
Cynthia J. M. Nolte, Ph.D., RAC
Staff Consultant
c/o Medical Device Consultants, Inc.
49 Plain Street
North Attleboro, MA 02760

Re: K020571
Stöckert Centrifugal Pump Console
Regulation Number: 870.4360
Regulation Name: Nonroller-type cardiopulmonary bypass blood pump
Regulatory Class: Class II (two)
Product Code: DTQ
Dated: July 9, 2002
Received: July 11, 2002

Dear Ms. Nolte:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality

systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known):

Device Name: Stöckert Centrifugal Pump Console

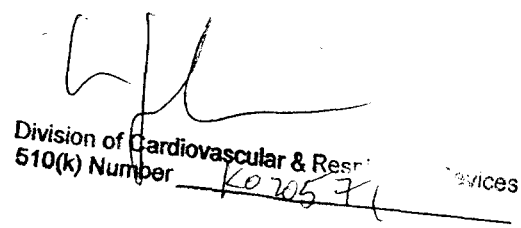
Indications for Use:

The Stöckert Centrifugal Pump Console (SCPC System) is a software-controlled cardiopulmonary bypass device containing an uninterruptable power supply (UPS) and S3 Sensor Modules that is designed for operation of the Stöckert Centrifugal Pump (SCP) and monitoring the cardiopulmonary bypass circuit. The SCPC System, in combination with the SCP and the COBE Revolution Pump Head, is indicated for speed-controlled pumping through the cardiopulmonary bypass circuit for typical durations of six hours or less.

The SCPC System has been qualified only for durations appropriate to cardiopulmonary bypass procedures and has not been qualified through in vitro, in vivo, or clinical studies, for long term use as a bridge to transplant, pending recovery of the natural heart, or extracorporeal membrane oxygenation (ECMO) procedures.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)



Prescription Use _____ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)